

X

**National Association of State Departments of Agriculture
(NASDA)**

Series of NASDA Proposed Resolutions, Passed by Membership

NASDA Policy Numbers 97-20 through 97-25

February 21, 1997

Each of these resolutions contain NASDA recommendations to the Environmental Protection Agency (EPA) for revising the pesticide emergency exemption program or process under Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act.

NOTE: This cover page was prepared by EPA for presentation of the following series of resolutions together in the public docket at docket ID # OPP-2002-0231

National Association of State Departments of Agriculture

1997 Proposed Resolution

Submitted by (organization): NASDA/AAPC Section 18 Task Force

Originating State: Virginia

Individual Contact: Dr. Marvin Laawson

Phone Number: 804/786-3501

Date submitted: February 21, 1997

NASDA Policy Number: 97-20

Action by Policy & Planning Committee:

Committee Assignment: Pesticide Regulation Committee

Committee Recommendation: Pass

Action by Membership: Pass

CRITERIA FOR SIGNIFICANT ECONOMIC LOSS; THE OCCURRENCE OF A NON-ROUTINE EVENT; AND DEFINITION OF AN EMERGENCY CONDITION

BACKGROUND

Economic data can be highly dependent on a number of factors outside the control of the producer of the crop. These factors include such things as the pricing structure of the specific commodity, government subsidies, variations in the acreage planted, size of the crop, and export variations. These factors can cause profits/losses to fluctuate dramatically from year-to-year and mask the emergency nature of the situation.

AAPCO/NASDA POSITION

AAPCO/ NASDA supports the following actions by Environmental Protection Agency (EPA):

- seek changes to current regulations which will allow EPA the flexibility to base decisions on crop yield as opposed to crop value (or profit loss) in situations where that is a better indicator of pest damage suffered;
- provide states general guidance regarding the appropriate documentation of an "urgent, non-routine situation" and allow states to certify that the "urgent, non-routine situation" exists based on the guidance; and
- implement a performance audit program to ensure compliance with the guidance and give states justification to resist pressure to certify an "urgent, non-routine situation" when it does not exist.

IMPACT

Allowing the states to determine and certify that an "urgent, non-routine situation" exists will free up agency resources while spot performance audits will help continue to ensure the legitimacy of the determinations.

The use of yield data will allow states to more easily show the true nature of the emergency and make it easier for EPA reviewers to make a determination that an emergency situation exists.

The acceptance of expert testimony beyond the first year of an emergency exemption, and the elimination of the requirement to develop comparative efficacy data to support continued use under an emergency exemption, is important to the continued ability to obtain critical pest control tools for the producer.

National Association of State Departments of Agriculture

1997 Proposed Resolution

Submitted by (organization): NASDA/AAPC Section 18 Task Force
Originating State: Virginia
Individual Contact: Dr. Marvin Laawson
Phone Number: 804/786-3501
Date submitted: February 21, 1997

NASDA Policy Number: 97-21
Action by Policy & Planning Committee:
Committee Assignment: Pesticide Regulation Committee
Committee Recommendation: Pass
Action by Membership: Pass

SECTION 18 MULTI-YEAR ISSUANCE OF TOLERANCES AND DELEGATION OF AUTHORITY TO STATES FOR REISSUANCE IN EVENT OF CONTINUING EMERGENCY CONDITIONS

BACKGROUND

Currently, all Section 18 authority resides within the Environmental Protection Agency (EPA) headquarters. No authority is delegated to the EPA regional offices, nor the State Lead Agencies (other than the states' authority to request the Section 18 exemption). The regulations do provide for a state to issue a "crisis exemption" in situations involving an unpredictable emergency situation when, an emergency condition exists and the time element with respect to the application of the pesticide is critical, and there is not sufficient time either to request a specific, quarantine, or public health exemption, or if such request has been submitted, for EPA to complete review of the request. A crisis exemption may be authorized for no longer than 15 days, unless an application requesting a specific, quarantine, or public health exemption for the use has been submitted to the EPA. EPA must review each crisis exemption to determine if use of the pesticide may result in such unreasonable health or environmental risks that the crisis authority should not be exercised, or the crisis exemption should be revoked.

Under the Food Quality Protection Act (FQPA) states will continue to be allowed to issue "crisis exemptions" in special circumstances. However, those exemptions must now meet the new requirements for additional public health protection as well. The state will be assuming a very real risk that the treated crop would be determined to be adulterated, in the event that EPA does not establish a tolerance, or establishes the tolerance after the harvest date for a given crop.

Under the requirements of 40 CFR 166.28, the EPA can issue a public health or specific exemption for no more than one year. Currently, EPA ranks all actions/submissions under Section 18 on a "first come, first served" basis. While the Agency targets a 20-day turnaround for all scientific reviews and a 50-day overall turnaround for a decision to be issued, this timetable is rarely met.

While the current requirements under 40 CFR 166, prevent EPA from issuing multi-year specific or public health exemptions under Section 18, there is no limitation on the duration of a "time- limited tolerance," required by FQPA.

AAPCO/NASDA POSITION

AAPCO/NASDA supports the following actions by EPA:

- establish multi-year, time-limited tolerances for pesticides authorized under Section 18, for a minimum of three years, at the time the Agency grants the initial Section 18 request or re-authorizes for the first time under the new procedures (in developing regulations to implement the tolerance provision for Section 18, the Agency should make sure that they do not provide benefit to foreign producers or afford them rights to the detriment of domestic producers);
- delegate to the states authority to reissue the Section 18 exemption for a second and/or third year, based on the state's confirmation/certification that the basis for the emergency continues to exist; and
- actively support and coordinate regional Section 18 requests.

IMPACT

EPA will be able to conserve its internal resource—resources which could be better utilized in other Agency priority program areas (registration, re-registration). States will remain responsive to the needs of their agricultural producers, and be able to deal effectively with actual, documented emergency pest situations, for which there is no effective federally-registered product available.

The active promotion of regional requests will foster a heightened awareness of common problems and concerns; position the states, regions and EPA headquarters to best utilize all available resources; and eliminate the potential to place some states at an economic disadvantage with others. The coordination of Section 18 registrations which provided effective pest control products to combat late blight in potatoes and blue mold in tobacco in 1995 and 1996 has established a precedence for the regional approach and has demonstrated that it can be a very efficient approach. Agricultural producers will benefit from being able to better plan their integrated crop management strategies, by continuing to have access to those chemical pesticides which constitute a vital element in their pest management arsenal.

National Association of State Departments of Agriculture

1997 Proposed Resolution

Submitted by (organization): NASDA/AAPC Section 18 Task Force

Originating State: Virginia

Individual Contact: Dr. Marvin Laawson

Phone Number: 804/786-3501

Date submitted: February 21, 1997

NASDA Policy Number: 97-22

Action by Policy & Planning Committee:

Committee Assignment: Pesticide Regulation Committee

Committee Recommendation: Pass

Action by Membership: Pass

WILDLIFE MONITORING REQUIREMENTS FOR SECTION 18 REGISTRATIONS

BACKGROUND

Section 20 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) gives the Environmental Protection Agency (EPA) authority to undertake monitoring activities and establish procedures for monitoring "...animals...for incidental pesticide exposures." Section 20 goes on to state that "such activities shall be carried out in cooperation with other federal, state and local agencies." At a recent meeting of the (FIFRA) Scientific Advisory Panel, the panel concluded that field data for wildlife was necessary for pesticide registration. This requirement to monitor wildlife mortality is an expensive, resource intensive and time-consuming burden placed upon the states. In recent years, extensive documents have been sent to EPA reporting the results of avian monitoring. To date, none of these reports have shown avian mortality nor unusual adverse effects to any wildlife due to the provisional use of these pesticides.

AAPCO/NASDA POSITION

AAPCO/NASDA recommends the following EPA action:

- enter into discussions with the states to establish reasonable monitoring criteria and approaches for wildlife and endangered species.

IMPACT

Clear monitoring guidance, developed in cooperation with the states, will ensure that EPA's goal of protecting wildlife will be met. Providing states with additional funds will eliminate or reduce the additional resource burdens caused by the requirement to conduct monitoring for wildlife mortality. EPA may determine that it is appropriate to place a surcharge on registrants whose products pose an undue threat to wildlife, to cover the additional monitoring costs.

National Association of State Departments of Agriculture

1997 Proposed Resolution

Submitted by (organization): NASDA/AAPC Section 18 Task Force

Originating State: Virginia

Individual Contact: Dr. Marvin Laawson

Phone Number: 804/786-3501

Date submitted: February 21, 1997

NASDA Policy Number: 97-23

Action by Policy & Planning Committee:

Committee Assignment: Pesticide Regulation Committee

Committee Recommendation: Pass

Action by Membership: Pass

EMERGENCY EXEMPTIONS FOR RESISTANCE MANAGEMENT

BACKGROUND

The loss of effective pesticides due to the selection of pest populations that are resistant is a growing problem that could potentially return agriculture to the times of excessive pest related damage commonly experienced prior to the widespread availability of modern agricultural chemicals. Current interpretations of Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 18 require that pest resistance develop to the point that all registered products are rendered essentially useless before a Section 18 registration can be issued for an alternative pest control product.

AAPCO/NASDA POSITION

AAPCO/NASDA supports specific exemptions for resistance management where there is documented scientific evidence of resistance to currently registered pesticides or where valid research demonstrates that a dynamic process of resistance is developing.

IMPACT

The future success of resistance management depends on the continued availability of a diverse arsenal of efficacious pest management tools. Allowing use of the Section 18 process as proposed here would provide growers with an immediate and effective means of preserving pesticide efficacy.

National Association of State Departments of Agriculture

1997 Proposed Resolution

Submitted by (organization): NASDA/AAPC Section 18 Task Force

Originating State: Virginia

Individual Contact: Dr. Marvin Laawson

Phone Number: 804/786-3501

Date submitted: February 21, 1997

NASDA Policy Number: 97-24

Action by Policy & Planning Committee:

Committee Assignment: Pesticide Regulation Committee

Committee Recommendation: Pass

Action by Membership: Pass

FEDERAL PESTICIDE EXEMPTIONS BASED ON REDUCED RISK

BACKGROUND

Current regulations and guidance do not allow for Environmental Protection Agency (EPA) to consider a request for a Section 18 that would allow the use of a pesticide in order to reduce one or more risks associated with the currently available pesticides or other pest control practices in common practice at the time of the request. The Food Quality Protection Act (FQPA) has greatly expanded the requirements for registration of new active ingredients thus increasing the data and time that will be required to register a pesticide product under (Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 3.

AAPCO/NASDA POSITION

It is the position of AAPCO/NASDA that EPA should amend Title 40 CFR Section 166.2 to include "reduced risk" as an acceptable basis for granting a Section 18 exemption. The definition of "reduced risk," and the requirements for this request, should allow states the ability to request a Section 18 to allow for a pesticide use that will result in a lower potential for an adverse impact on human health or any other non-target species, including but not limited to, pest predators, pollinators, endangered species, and other organisms of special concern. Requests should be limited to only those situations where the "reduced risk" request will not result in additional risk to any aspect of the environment. Such requests should only be permitted where the proposed use is highly effective so that the potential for an increase in pesticide applications is extremely low.

IMPACT

To implement "reduced risk" as a basis for Section 18 requests will require amending the current regulations, and will likely result in the states having to screen a significantly increased number of Section 18 requests. EPA may also have to review an increased number of requests. However, any disadvantage in the increase in the number of Section 18 requests that the states and EPA may have to process due to this option should be far out weighed by the enhanced ability to provide for the protection of human health and the environment, while providing growers with acceptable pest controls.

National Association of State Departments of Agriculture

1997 Proposed Resolution

Submitted by (organization): NASDA/AAPC Section 18 Task Force

Originating State: Virginia

Individual Contact: Dr. Marvin Laawson

Phone Number: 804/786-3501

Date submitted: February 21, 1997

NASDA Policy Number: 97-25

Action by Policy & Planning Committee:

Committee Assignment: Pesticide Regulation Committee

Committee Recommendation: Pass

Action by Membership: Pass

ESTABLISHING TOLERANCES FOR SECTION 18s UNDER THE FQPA

BACKGROUND

The Food Quality Protection Act (FQPA) of 1996 set a new standard for Section 18 emergency exemptions by requiring the United States Environmental Protection Agency (EPA) to set a time-limited tolerance for pesticide residues. EPA's current approach to setting the required tolerances has resulted in considerable delays in approval of Section 18s, or outright denial because of risk considerations. Congressional staff discussing this issue before the Food Safety Advisory Committee indicated that the intent was to provide an enforceable standard, not to inhibit the Agency's ability to issue Section 18s. Unfortunately, delays have resulted in significant economic impacts.

In establishing a tolerance for Section 18 emergency exemptions, EPA must use the same "safe" standard that applies to pesticides registered under Section 3. However, EPA has considerable discretion under the law in interpreting the new standard. Currently, EPA considers a 100-fold safety factor applied to the scientifically determined "no observable effect" level extrapolated from animal studies to be a "safe" level for threshold effects. EPA considers an increase of no more than one-in-a-million life time risk in a quantitative risk analysis to be a "safe" level for non-threshold effects. The legislative history of FQPA makes it clear that the Agency can change its interpretation and risk assessment policy. Congress expects that any changes in approach will be clarified in the regulations that the Agency will promulgate to implement the specific tolerance provision. While EPA may not have flexibility in *whether* to establish a tolerance for Section 18 emergency exemptions, the Agency clearly has the flexibility and authority to determine *how* it will establish those tolerances.

Data and Default Assumptions

When considering factors such as aggregate and cumulative exposures, when establishing a tolerance, FQPA stipulates the use of available information. Thus, using all of the factors for setting or reassessing a tolerance in the absence of data is not mandated. EPA should not rush to set default assumptions for these factors in the absence of data.

Aggregate Exposure

Aggregate exposure is defined as "anticipated dietary exposure and all other exposures for which there is reliable information." (emphasis added) In other words, if there is no other reliable information on other exposures, the determination of safety can and must be made based on dietary exposure alone, that being the aggregate exposure. The new language provides an elaborate statutory scheme for calling in new data to use in future determinations. However, in the absence of that data, worst-case scenario assumptions, or default assumptions, are not required.

Cumulative Risk

Another notable default assumption is the use of "mode" or "mechanism" of "action" instead of the FQPA standard of "mechanism of toxicity." While this latter term often refers to the molecular or biochemical changes induced by a chemical, the "mode" often refers to organ-level toxicity/changes. Because there is limited information on mechanism of toxicity of chemical, but more readily available information on "mode" of toxicity, it is EPA's intent to use the latter as a surrogate. In grouping chemicals together for evaluating cumulative risk, the assumption that toxic effects are additive may not be appropriate without knowledge of the biochemical or molecular interaction at the cellular level.

Safety Factor for Infants and Children

The Federal Food, Drug and Cosmetic Act (FFDCA) Section 408(B) deals with the authority and standard for tolerance setting by the Administrator. The new language, found in (b)(2)(C), relates to the special steps the Administrator must take to address the needs of infants and children when setting tolerances. The Administrator must "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure...."

When dealing with threshold effects, this section states that the Administrator shall use an additional ten-fold margin of safety when setting tolerances for residues of chemicals which may be used on commodities which occur at a disproportionately high level in the diets of infants and children. However, this section specifically provides that the Administrator may use a different margin of safety if, on the basis of reliable data, it would be "safe for infants and children."

International Trade Components

The requirement for a Section 18 tolerance also has the effect of correcting a prior perceived trade by allowing importation of foods containing pesticide residues within Section 18 tolerances. Previously, due to the lack of a tolerance, imported foods with pesticide residues, which would be permissible on domestically produced foods under a Section 18 exemption were considered adulterated. This resulted in preferential treatment of domestically-produced food and discrimination against foods from other countries in potential violation of the U.S.'s agreement under the General Agreement on Trade and Tariffs (GATT).

EPA should account for the Administration's interpretation of what GATT requires. The Agency's primary mandate under FQPA is food safety, not non-discrimination. How the Agency accounts for the relative contribution of domestic and foreign produce in its dietary exposure assessment will be crucial. In developing regulations to implement the tolerance provision for Section 18, the Agency should make sure that they do not provide benefit to foreign producers or afford them rights to the detriment of domestic producers.

Registrant Disincentives

The use of all of the factors outlined in FQPA for tolerance determination in establishing the time-limited tolerances for Section 18 uses, and incorporating a set of default assumptions in lieu of available data, establishes disincentives for registrants to support Section 18 uses.

Alternative Approach to Assessing the Short-Term Exposure from Section 18 Pesticide Use

Currently, EPA is using the "risk cup" concept for all tolerance determinations. For setting time-limited tolerances for Section 18, it can be argued that a separate short-term "risk cup" should be used.

AAPCO/NASDA POSITION

While EPA has no discretion regarding establishment of a time-limited tolerance for pesticide residues in or on food for Section 18 emergency exemptions, it is AAPCO/NASDA's position that the EPA exercise its broad discretionary authority in determining how it will establish the tolerance and analyze the risks associated with pesticide residues. Consistency among different EPA programs is recommended.

In the absence of available information, we recommend that the EPA not rush to establish default assumptions that are not required—and perhaps not permissible—under the language of FQPA.

The temporary nature of Section 18 exposure argues for separate "risk cup" calculations.

Finally, we recommend that the EPA use common sense in determining whether to grant Section 18 emergency exemptions and tolerances. EPA should not deny Section 18 applications for use of pesticides that has resulted in non-detectable residues and pose no additional risk.

IMPACT

The current EPA approach to establishing time-limited tolerances for Section 18 registrations, in order to comply with the requirements of FQPA, has resulted in considerable delays in approval of Section 18s, or outright denial because of risk considerations. Unfortunately these delays have resulted in significant economic impacts.

Adoption of the above recommendations will ensure that appropriate pest control chemicals are available to address emergency pest situations that may be experienced by the nation's agricultural producers while continuing to protect human health, as required by the FQPA.